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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/813,384 | 03/30/2004 | Reuben Edwin Deloach | | 4710 |

7590 03/29/2006

REUBEN E. DELOACH
3916 LINKMEADOW DR.
FORT WORTH, TX 76008

EXAMINER

DAVIS, BRIAN J

ART UNIT PAPER NUMBER

1621

DATE MAILED: 03/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|-----------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/813,384 | DELOACH, REUBEN EDWIN | |
| | Examiner | Art Unit | |
| | Brian J. Davis | 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-25 is/are rejected.
- 7) ☒ Claim(s) 23 and 25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/3/06</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

Three references which appear on the 1/3/06 IDS have been lined-through as they are duplicates of references already of record in the application.

Specification

The substitute specification filed 1/3/06 has not been entered because it does not conform to 37 CFR 1.125(b) and (c) because: it contains new matter. See MPEP 608.01(q). As applicant explicitly admits on page 2 of the 1/3/06 Reply, the entire application (specification and claims) has been rewritten in response to the art and arguments presented in the previous Office Action. Thus, per force, the specification contains new matter.

The examiner notes for clarity of the record that although the substitute specification has not been entered, in accordance with MPEP 714.20 in cases such as the instant application, the new claims have been entered.

Claim Objections Withdrawn

The objection to claim 4, outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment cancels the claim.

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112 Rejections Withdrawn, FIRST PARAGRAPH

The rejection of claims 5-18 under 35 USC 112, first paragraph, outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment cancels the claims.

112 Rejections Withdrawn, SECOND PARAGRAPH

The rejection of claims 6-11 and 20 under 35 USC 112, second paragraph, outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment cancels the claims.

102 Rejections Withdrawn

The rejection of claims 1-5, 19 and 20 under 35 USC 102(b), outlined in the previous Office Action, has been overcome by applicant's amendment. The amendment cancels the claims.

NEW, Claim Objections

Claims 23 and 25 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim can only depend in the alternative from a preceding claim. See MPEP § 608.01(n).

NEW, Claim Rejections - 35 USC § 112, FIRST PARAGRAPH

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As applicant explicitly admits on page 2 of the 1/3/06 Reply, the entire application (specification and claims) has been rewritten in response to the art and arguments presented in the previous Office Action. Thus, the claims, per force, contain new matter.

Claims 21-25 are also rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for reasons of record in the previous Office Action and elaborated on as follows:

"A process is reduced to practice when it is successfully performed." *Corona v. Dovan*, 273 US 692, 1928 CD 252 (1928). This applicant clearly has not done. As was stated in the previous Office Action, applicant provides no working examples, laboratory or clinical data or, indeed, any evidence whatsoever, that the claimed methods are efficacious. The closest applicant comes to presenting such experimental data is to cite in the 1/3/06 Reply the data of others (who neither teach nor suggest applicant's claimed subject matter) as, one must surmise, indirect experimental evidence for the instant claims. This is as extraordinary as it is insufficient.

Case law is well settled on this point: in unpredictable arts such as chemistry, biology or medicine, there must be a simultaneous conception and reduction to practice of the invention. See MPEP 715.07, 2138.01 and 2138.05. See also the discussion in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* (CAFC) 18 USPQ2d 1016 (1991). The instant claimed invention has not been reduced to practice. As was stated in the previous Office Action, the claimed subject matter remains, at best, a hypothesis.

NEW, Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Although the claims appear to be based upon a Jepson formate, the claims are generally narrative and indefinite, failing to conform with current U.S. practice.

NEW, Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 21-25 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by applicant's own admission in the original specification (page 1 paragraphs 0002 and 0004) that this invention provides a new use for existing drugs of the MAOI class.

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However, as was pointed out in the previous Office Action, claims are unpatentable where the prior art process per se of applying the chemical is the same, notwithstanding applicant's different purpose for application of the compound. In re Kirby, 40 USPQ 368. This is so because a compound and its properties are inseparable. *In re Papesch*, 315, F.2d 381, 137 USPQ 43 (CCPA 1963).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

This action is a **final rejection** and is intended to close the prosecution of this application. Applicant's reply under 37 CFR 1.113 to this action is limited either to an appeal to the Board of Patent Appeals and Interferences or to an amendment which permits allowance of the claims (not possible in the instant case). If applicant should desire to appeal any rejection made by the examiner, a Notice of Appeal must be filed within the period for reply identifying the rejected claim or claims appealed. The Notice of Appeal must be accompanied by the required appeal fee.

An examination of this application, and applicant's own admission, reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. If applicant wishes to continue,

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applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution.

The Office cannot aid in selecting an attorney or agent, however, a listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450.

If applicant should desire to file an amendment, entry of a proposed amendment after final rejection cannot be made as a matter of right unless it merely cancels claims or complies with a formal requirement made earlier. Amendments touching the merits of the application which otherwise might not be proper may be admitted upon a showing a good and sufficient reasons why they are necessary and why they were not presented earlier.

A reply under 37 CFR 1.113 to a final rejection must include the appeal from, or cancellation of, each rejected claim. The filing of an amendment after final rejection, whether or not it is entered, does not stop the running of the statutory period for reply to the final rejection unless the examiner holds the claims to be in condition for allowance. Accordingly, if a Notice of Appeal has not been filed properly within the period for reply, or any extension of this period obtained under either 37 CFR 1.136(a) or (b), the application will become abandoned.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Davis whose telephone number is 571-272-0638. The examiner can normally be reached on 8:30-5:00.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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 **BRIAN DAVIS**
PRIMARY EXAMINER
Brian J. Davis
March 21, 2006